



Food and Drug Administration  
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June 19, 2015

Genadyne Biotechnologies Incorporated  
Chien-Ming Goh  
Vice President, Regulatory Affairs  
16 Midland Avenue  
Hicksville, New York 11801

Re: K143726

Trade/Device Name: Genadyne XLR8 Plus (XLR8+) Negative Pressure Wound Therapy  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered suction pump  
Regulatory Class: Class II  
Product Code: OMP  
Dated: May 14, 2015  
Received: May 18, 2015

Dear Chien-Ming Goh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143726

Device Name

Genadyne XLR8 Plus (XLR8+) Negative Pressure Wound Therapy

Indications for Use (Describe)

The XLR8 Plus (XLR8+) Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Traditional 510k Summary**  
**Negative Pressure Wound Therapy**

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Hicksville, NY 11801

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**Contact Person:** Mr. Chien-Ming GOH (Andrew)

**Date Prepared:** December 23, 2014

**Name of Device**

XLR8 Plus (XLR8+) Negative Pressure Wound Therapy

**Common or Usual Name**

Powered Suction Pump

**Classification Name**

OMP, Negative Pressure Wound Therapy Powered Suction Pump

21 C.F.R. § 878.4780

**Predicate Device**

A4-XLR8 Wound Vacuum System, K090638

**Device Description**

The XLR8 Plus (XLR8+) Wound Vacuum System is a portable, rechargeable battery powered wound suction pump with the intention to generate negative pressure to remove exudate from the wound.

**Intended Use / Indications for Use**

The XLR8 Plus (XLR8 +) Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

## Technological Characteristics

Table of Comparison to Predicate Devices:

<b><u>Comparative Information</u></b>		
	<b><u>Predicate Device</u></b>	<b><u>New Device</u></b>
Company	Genadyne Biotechnologies	Genadyne Biotechnologies
Device Name	A4-XLR8 Wound Vacuum System	XLR8 Plus (XLR8+) Wound Vacuum System
510 (K) Number	K090638	
<b><u>Technical Data</u></b>		
<i>Suction Capacity</i>	3.5 liters per minute	> 5 liters per minute
<i>Max Vacuum</i>	230 mmHg	230 mmHg
<i>Power Requirements</i>	30W	30W
<i>Battery Type</i>	Rechargeable Li-Ion	Rechargeable Li-Ion
<i>Dimensions / Weight</i>	5.9" x 4" x 2.4" / 1.5 lbs	5.9" x 4" x 3.4" / 1.65 lbs
<b><u>Accessories</u></b>		
<i>Canisters</i>	200, 400, 600, 800 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection	200, 400, 600, 800 & 1100 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection
<b><u>Reusable</u></b>	No	No
<b><u>Sterile</u></b>	Non Sterile	Non Sterile
<b><u>Accessory Kit</u></b>		
	A4-XLR8 Foam Dressing (K092992)	A4-XLR8 Foam Dressing (K092992) XLR8 Bridge Dressing XLR8 Port Pad XLR8 Transparent Film Gauze Dressing with Silicone Drain Gauze Dressing with XLR8 Port Pad
<b><u>Indications for Use</u></b>		
	Genadyne A4-XLR8 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound	Genadyne XLR8 Plus Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the

	healing by the removal of excess exudates, infectious material and tissue debris.	removal of excess exudates, infectious material and tissue debris.
<b><u>Contraindications</u></b>		
	The Genadyne A4-XLR8 is contraindicated in the presence of :	The Genadyne XLR8 Plus is contraindicated in the presence of:
	- Necrotic tissue	Necrotic tissue
	- Untreated osteomyelitis	Untreated osteomyelitis
	- Malignancy (with exception to enhance quality of life)	Malignancy (with exception to enhance quality of life)
	- Untreated malnutrition	Untreated malnutrition
	- Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
<b><u>Precautions</u></b>		
	Precautions should be taken for patients who are or may be:	Precautions should be taken for patients who are or may be:
	- Receiving anticoagulant therapy	Receiving anticoagulant therapy
	- Suffering from difficult hemostasis	Suffering from difficult hemostasis
	- Untreated for malnutrition	Untreated for malnutrition
	- Non-complaint or combative	Non-complaint or combative
<b><u>Compliance</u></b>		
	IEC 60601-1, 3 <sup>rd</sup> Edition	IEC 60601-1
		IEC 60601-1-2
<b><u>Storage / Transport</u></b>		
	-18°C to +43°C (0°F to 110°F)	-18°C to +43°C (0°F to 110°F)
	Relative Humidity 10% to 95 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 – 1060 mbar Atmospheric pressure
<b><u>Operation</u></b>	18°C to 34°C (65°F to 94°F)	18°C to 34°C (65°F to 94°F)
	Relative Humidity 10% to 95 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 - 1060 mbar Atmospheric pressure

15. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 Plus (XLR8+) is substantially equivalent to the predicate device.